

Food and Drug Administration, HHS

§ 173.385

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	Limitations
Cellulose triacetate	May be used as a fixing material in the immobilization of lactase for use in reducing the lactose content of milk.
Diethylaminoethyl-cellulose	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
Glutaraldehyde	Do.
Periodic acid (CAS Reg. No. 10450-60-9) ..	
Polyethylenimine reaction product with 1,2-dichloroethane (CAS Reg.No. 68130-97-2) is the reaction product of homopolymerization of ethylenimine in aqueous hydrochloric acid at 100 °C and of cross-linking with 1,2-dichloroethane. The finished polymer has an average molecular weight of 50,000 to 70,000 as determined by gel permeation chromatography. The analytical method is entitled "Methodology for Molecular Weight Detection of Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-200), 200 C St. SW., Washington, DC 20204, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC..	May be used as a fixing material in the immobilization of glucoamylase enzyme preparations from <i>Aspergillus niger</i> for use in the manufacture of beer. May be used as a fixing material in the immobilization of: 1. Glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter. 2. Glucoamylase enzyme preparations from <i>Aspergillus niger</i> for use in the manufacture of beer. Residual ethylenimine in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography-mass spectrometry. The residual ethylenimine is determined by an analytical method entitled "Methodology for Ethylenimine Detection in Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Residual 1,2-dichloroethane in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography. The residual 1,2-dichloroethane is determined by an analytical method entitled, "Methodology for Ethylenedichloride Detection in Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-215), 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) The fixed enzyme preparation is washed to remove residues of the fixing materials.

[48 FR 5716, Feb. 8, 1983, as amended at 52 FR 39512, Oct. 22, 1987; 55 FR 12172, Apr. 2, 1990; 59 FR 36937, July 20, 1994; 61 FR 4873, Feb. 9, 1996; 61 FR 14245, Apr. 1, 1996]

§ 173.360 Octafluorocyclobutane.

The food additive octafluorocyclobutane may be safely used as a propellant and aerating agent in foamed or sprayed food products in accordance with the following conditions:

(a) The food additive meets the following specifications:

99.99 percent octafluorocyclobutane.
Less than 0.1 part per million fluoroolefins, calculated as perfluoroisobutylene.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, and propane, as a propellant and aerating agent for foamed or sprayed food products, except for those

standardized foods that do not provide for such use.

(c) To assure safe use of the additive:

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, octafluorocyclobutane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.385 Sodium methyl sulfate.

Sodium methyl sulfate may be present in pectin in accordance with the following conditions.

(a) It is present as the result of methylation of pectin by sulfuric acid and methyl alcohol and subsequent treatment with sodium bicarbonate.

(b) It does not exceed 0.1 percent by weight of the pectin.

§ 173.395 Trifluoromethane sulfonic acid.

Trifluoromethane sulfonic acid has the empirical formula $\text{CF}_3\text{SO}_3\text{H}$ (CAS Reg. No. 1493-13-6). The catalyst (Trifluoromethane sulfonic acid) may safely be used in the production of cocoa butter substitute from palm oil (1-palmitoyl-2-oleoyl-3-stearin) (see § 184.1259 of this chapter) in accordance with the following conditions:

(a) The catalyst meets the following specifications:

Appearance, Clear liquid.

Color, Colorless to amber.

Neutralization equivalent, 147–151.

Water, 1 percent maximum.

Fluoride ion, 0.03 percent maximum.

Heavy metals (as Pb), 30 parts per million maximum.

Arsenic (as As), 3 parts per million maximum.

(b) It is used at levels not to exceed 0.2 percent of the reaction mixture to catalyze the directed esterification.

(c) The esterification reaction is quenched with steam and water and the catalyst is removed with the aqueous phase. Final traces of catalyst are removed by washing batches of the product three times with an aqueous solution of 0.5 percent sodium bicarbonate.

(d) No residual catalyst may remain in the product at a detection limit of 0.2 part per million fluoride as determined by the method described in "Official Methods of Analysis of the Association of Official Analytical Chemists," sections 25.049–25.055, 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[43 FR 54237, Nov. 11, 1978, as amended at 49 FR 10106, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 173.400 Dimethyldialkylammonium chloride.

Dimethyldialkylammonium chloride may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by one of the following methods:

(1) Ammonolysis of natural tallow fatty acids to form amines that are subsequently reacted with methyl chloride to form the quaternary ammonium compounds consisting primarily of dimethyldioctadecylammonium chloride and dimethyldihexadecylammonium chloride. The additive may contain residues of isopropyl alcohol not in excess of 18 percent by weight when used as a processing solvent.

(2) Ammonolysis of natural tallow fatty acids to form amines that are then reacted with 2-ethylhexanal, reduced, methylated, and subsequently reacted with methyl chloride to form the quaternary ammonium compound known as dimethyl(2-ethylhexyl) hydrogenated tallow ammonium chloride and consisting primarily of dimethyl(2-ethylhexyl)octadecylammonium chloride and dimethyl(2-ethylhexyl)hexadecylammonium chloride.

(b) The food additive described in paragraph (a)(1) of this section contains not more than a total of 2 percent by weight of free amine and amine hydrochloride. The food additive described in paragraph (a)(2) of this section contains not more than 3 percent by weight, each, of free amine and amine hydrochloride as determined by A.O.C.S. method Te 3a-64, "Acid Value and Free Amine Value of Fatty Quaternary Ammonium Chlorides," 2d printing including additions and revisions 1990, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and from the American Oil Chemists' Society, P.O. Box 5037, Station A, Champaign, IL 61820, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(c) The food additive is used as a de-colorizing agent in the clarification of